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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,532	08/03/2001	Endre Markovits Schersl	06965-1001	9018
7590 02/09/2004				
BAKER & McKENZIE 12th Floor 101 West Broadway San Diego, CA 92101			EXAMINER BADIO, BARBARA P	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,532

Applicant(s)

SCHERSL ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-35 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 11 and 13-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2003 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

3. Newly submitted claims 10 and 12 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The instant claims recite a method of making a composition whereas the original invention was drawn to a composition and method of using said composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10 and 12 are withdrawn from

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consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

4. The provisional rejection of claims 1-9 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/772,790 is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11, 14, 15 and 21-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The wt % of each policosanol and/or phytosterol as recited by the instant claims does not find support in the original disclosure.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 14-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 are indefinite because they are in improper dependent form, i.e., they are drawn to compositions but are dependent on process claims. Claims 16-35 are dependent claims and, thus, are rejected for the same reason.

Claim Rejections - 35 USC § 102

9. The rejection of claims 1, 3, 4, 5 and 9 under 35 USC 102(b) over Sorkin, Jr. ('393) is made moot by the cancellation of the instant claims.

Claim Rejections - 35 USC § 103

10. The rejection of claims 1-9 under 35 USC 103(a) over Sorkin, Jr. ('393), Maurel et al. ('924) and Perez ('354) in combination is made moot by the cancellation of the instant claims.

11. Claims 11 and 13-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorkin, Jr. ('393), Gamble et al. ('776); Maurel et al. ('924) and Milstein et al. ('230) in combination.

Sorkin teaches a composition comprising phytosterols and policosanols for reducing serum cholesterol levels (see the entire article, especially col. 1, lines 5-8; col. 3, lines 11-26; examples 1 and 2). The reference teaches (a) phytosterols such as β -

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sitosterol, campesterol and stigmasterol and (b) policosanols ranging from 20 to 39 carbon atoms in length, such as docosanol, tetracosanol, hexacosanol and octacosanol (see col. 2, lines 27-31 and Table I; col. 3, Table II).

Gamble et al. teach a mixture comprising aliphatic alcohols containing 20 to 34 carbon atoms and their use in pharmaceutical compositions, foodstuffs and dietary supplements (see the entire article, especially Abstract; col. 4, lines 20-28; col. 5, lines 47-56 and col. 9, lines 44-63).

Maurel et al. teach phytosterols are known hypocholesterolaemic agents. The reference also teaches the incorporation of said agents into food products such as margarine (see col. 2, lines 33-46).

Milstein et al. teach phytosterols are known to be effective in reducing serum cholesterol and its incorporation into food products (see col. 1, lines 18-35). The reference also teaches (a) food additive containing sterol or stanol ester of a fatty acid and (b) the incorporation of said additives into food products for the purpose of lowering serum cholesterol (see the entire article, especially col. 1, lines 39-45).

Sorkin makes obvious a composition comprising phytosterols and policosanols. In addition, Gamble, Maurel and Milstein teach the utilization of the recited ingredients in compositions useful for reducing serum cholesterol levels. It has been held that the combination of two or more composition having similar use to form another composition for the same use is prima facie obvious. Therefore, applicant's claimed composition is prima facie obvious based on the teachings of the prior art.

The recitation of the specific wt % of each phytosterol and policosanols in the claimed composition is noted. However, the court has held that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Russell, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971). Applicant has not provided any reason(s) why the amounts of each policosanols and phytosterol as recited by the instant claims are critical to the instant invention.

Response to Applicant's argument

12. Applicant argues the policosanols composition of the instant invention is strikingly different from that taught by the prior art. Applicant argument was considered but not persuasive for the following reasons.

As indicated above in #11, in the absence of a showing of criticality of the proportions and ranges, applicant's composition is not patentable over that taught by the prior.

Applicant also argues that the claimed composition is a unique combination of policosanols. However, Sorkin teaches a composition comprising policosanols ranging from 20 to 39 carbon atoms. If by unique, applicant is referring to the presence of other policosanols in the prior art composition, it should be noted that the use of the transitional term "comprising", which is synonymous with "including", "containing" or "characterized by" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps (see MPEP 2111.03). Therefore, applicant's claimed policosanols composition reads on that taught by prior art. In addition, based on the

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teachings of the prior art, policosanols are known to have hypocholesterolaemic properties and, thus, the combination of two or more of said agents to form another composition that is to be used for the very same purpose would be prima facie obvious. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
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